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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/628,998	07/28/2003	Tracee Eidenschink	S63.2-10692	7353
490	7590	06/02/2005		EXAMINER
VIDAS, ARRETT & STEINKRAUS, P.A. 6109 BLUE CIRCLE DRIVE SUITE 2000 MINNETONKA, MN 55343-9185			WILLIAMS, CATHERINE SERKE	
			ART UNIT	PAPER NUMBER
			3763	

DATE MAILED: 06/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/628,998	EIDENSCHINK, TRACEE
	<b>Examiner</b>	<b>Art Unit</b>
	Catherine S. Williams	3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 14 December 2004.
- 2a) This action is FINAL.                            2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) 14 and 26-32 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-13, 15-25 and 33-38 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>10/18/04; 10/27/03</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|   | 6) <input type="checkbox"/> Other: _____                                    |

## DETAILED ACTION

### *Election/Restrictions*

Applicant's election of Species I and subspecies b corresponding to figures 1 and 4 in the reply filed on 12/14/04 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 14 and 26-32 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 12/14/04.

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Giba et al (USPN 5,876,373). Giba discloses a catheter (100), an inner shaft (114,120,130) and an outer shaft (127) and a heat transmitting mechanism (130). The inner shaft or the outer shaft has a predetermined longitudinal stiffness at a predetermined temperature at the portion where the heat transmitting mechanism resides. See figures 10-11. The stiffness is changed when the temperature is changed. See 9:61+ for shape memory disclosure. As shown in figures 10-11 the inner layer is constructed of three layers: 1) 114, 2)120 and 3)130.

Claims 1-8 and 24-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Danforth (USPN 4,822,345). Danforth discloses a catheter (20), an inner shaft (53) and an outer shaft (42) and a heat transmitting mechanism (lumen 56). The assembly also has a balloon (28). It is considered inherent that any portion of the external surface of any balloon defines a stent mounting region.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 20-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Giba. Giba meets the claim limitations as described above but fails to include the materials as claimed.

At the time of the invention, it would have been an obvious design choice by one skilled in the art to use the claimed materials. Applicant has not stated that the claimed materials solve a stated problem, are used for a particular purpose or provides an advantage. Furthermore one would expect applicant's invention and the prior art materials to perform equally considering both applicant's invention and the prior art are utilized in the same function and perform equally well with their own materials.

Claims 2-8,10-13,15-17 and 33-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Giba in view of Ueda (USPN 4,799,474).

Giba meets the claim limitations as described above but fails to include (i) the heat transmitting mechanism extending distally from the proximal end of the catheter, (ii) a transmission lumen, (iii) a fluid source.

Ueda discloses a medical catheter that includes a steering mechanism having a shape memory wire (44A,44B) with a heat conducting tube (90) for changing the temperature and shape of the shape memory wire. See figure 21 and 7:36-54. The system inherently includes a fluid source. As shown in the drawings the wall thickness of tube (90) is about 0.001 in or less and has a diameter of about 0.003 in.

At the time of the invention, it would have been obvious to incorporate the pipe (90) of Ueda into the invention of Giba as a mechanism for carrying out procedure as disclosed. Giba states that the memory recall of the wire (130) can be produced by circulating heated fluid but does not provide a structure mechanism for carrying out the procedure. One skilled in the art would recognize that the pipe structure (90) of Ueda if incorporated into Giba would enable one to circulate a fluid to the wire (130) and control the stiffness and bending of the catheter.

Claims 9 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Giba in view of Ueda. Giba in view of Ueda meet the claim limitations as described above but fails to include the materials as claimed.

At the time of the invention, it would have been an obvious design choice by one skilled in the art to use the claimed materials. Applicant has not stated that the claimed materials solve a

stated problem, are used for a particular purpose or provides an advantage. Furthermore one would expect applicant's invention and the prior art materials to perform equally considering that both materials could transfer fluid equally well to the shape memory wires.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catherine S. Williams whose telephone number is 571-272-4970. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas D. Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*Catherine S. Williams*  
Catherine S. Williams  
May 26, 2005